K120962

APR 27 2012

entellus MEDICAL™

510(k) Summary

Date Prepared: March 29, 2012

Submitter Information:
Entellus Medical, Inc.
6705 Wedgwood Court, North
Maple Grove, MN 55311

Establishment Registration: 3006345872

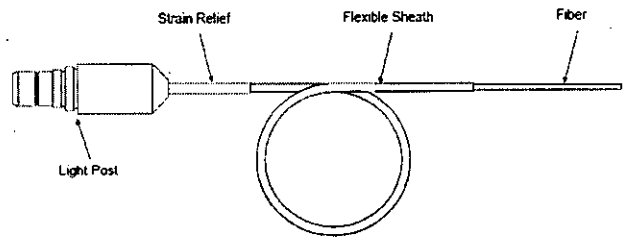
Contact Information:
Garrett P. Ahlborg
Regulatory Affairs Specialist
(763) 463-7074
gahlborg@entellusmedical.com

Device Information:

Trade Name:	PathAssist™ Light Fiber™
Common Name:	Sinus Guidewire
Classification Name:	ENT Manual Surgical Instrument
Product Code:	LRC
Regulation Number:	Class I, 21 CFR 874.4420

Predicate Device:
PathAssist™ Light Fiber™ [K111763]

Device Description:
The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a fiber nominal working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm. The Light Fiber is provided sterile and is for single use only.



PathAssist Light Fiber

The Light Fiber is packaged with a commercially available male tuohy borst adapter and a sinus cannula.

Indications for Use:
To locate, illuminate within, and transilluminate across nasal and sinus structures in patients aged 18 and over.

Contraindications:
None

Technological Characteristics:
The Light Fiber has the same indications for use and fundamental scientific technology as the predicate device [K111763]. The subject device has the same technological characteristics (i.e., principle of operation, design, function, materials, biocompatibility and sterility) as the predicate device.

Substantial Equivalence:
The Light Fiber has the same indications for use and fundamental scientific technology as the predicate device. The Light Fiber is substantially equivalent to the predicate device.

Performance Data:
Performance testing of the Light Fiber consisted of design verification testing. Design verification testing included functional testing to support compatibility of the Light Fiber with LED light sources. Sterilization, shelf life, packaging testing, biocompatibility, animal and clinical data were not submitted. Performance testing demonstrated that the subject device meets design specifications and performs as intended.

Conclusion:
In conclusion, the indications for use and technological characteristics are the same as or equivalent to the predicate device. Performance testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Entellus Medical, Inc.
% Garrett P. Ahlborg
6705 Wedgwood Court North
Maple Grove, MN 55311

APR 27 2012

Re: K120962
Trade/Device Name: PathAssist ™ Light Fiber™
Regulation Number: 21 CFR 874.4420
Regulation Name: ENT Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: March 29, 2012
Received: March 30, 2012

Dear Mr. Ahlborg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose, Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. Indications for Use Statement

510(k) Number (if known): K120962

Device Name: PathAssist™ Light Fiber™

Indications for Use

To locate, illuminate within, and transilluminate across nasal and sinus structures in patients aged 18 and over.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use____X_____- OR/AND Over-the-Counter Use_____

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120962